

What is claimed is:

1. A method of making a dosage form containing a first medicant, which comprises

- 5                   a) injecting through a nozzle a flowable material containing said first medicant into a mold cavity; and
- b) hardening said flowable material into a molded dosage form having a shape substantially the same as the mold cavity.

10                   2. The method of claim 1, further comprising the step of heating said flowable material prior to injecting said flowable material into said mold cavity, and wherein said hardening step (b) comprises cooling said flowable material.

15                   3. The method according to claim 2, wherein said mold cavity is heated prior to said injecting step (a) and cooled during said hardening step (b).

20                   4. The method according to claim 3, wherein said mold cavity is heated and cooled using heat transfer fluids that circulate proximal to said mold cavity.

25                   5. The method of claim 2, wherein said mold cavity is heated prior to said injection step (a) and cooled during said hardening step (b) using a single heat transfer fluid heated by a heat source and cooled by a heat sink.

30                   6. The method according to claim 1, wherein said flowable material comprises a polymer.

35                   7. The method according to claim 1, wherein said flowable material comprises a carbohydrate.

40                   8. The method according to claim 1, wherein said flowable material comprises a fat.

45                   9. The method according to claim 1, wherein said flowable material comprises a wax.

50                   10. The method according to claim 1, wherein said flowable material comprises gelatin.

11. The method according to claim 10, further comprising heating said gelatin to a temperature above its gel point prior to said injecting step (a), and wherein said hardening step (b) comprises cooling said gelatin to a temperature below its gel point.

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12. The method of claim 1, wherein said molded dosage form is substantially free of visible defects.

13. The method of claim 1, wherein substantially all of the flowable material injected into the mold cavity becomes part of the molded dosage form.

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14. The method according to claim 1, further comprising the step of placing an insert in said mold cavity prior to said injecting step (a), such that said molded dosage form comprises an insert embedded therein.

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15. The method according to claim 14, wherein said insert comprises a polymer.

16. The method according to claim 14, wherein said insert comprises a carbohydrate.

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17. The method according to claim 14, wherein said insert comprises a fat.

18. The method according to claim 14, wherein said insert comprises a wax.

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19. The method according to claim 14, wherein said insert comprises a second medicant.

20. The method according to claim 1 performed while said mold cavity is traveling along a circular path.

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21. A method of making a molded dosage form which comprises

- a) heating a flowable material;
- b) injecting said flowable material through an orifice into a mold cavity; and
- c) hardening said flowable material into a molded dosage form having a shape substantially the same as the mold cavity;

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wherein said hardening step (c) comprises cooling said flowable material and wherein said mold cavity is heated prior to said injecting step (b) and cooled during said hardening step (c).

5           22. The method of claim 21, wherein a medicant is introduced into the mold cavity prior to said hardening step (c).

23. A molded dosage form made according to the method of claim 21 substantially free of visible defects.

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24. A method of coating a substrate, comprising the steps of:

a) enclosing at least a portion of said substrate in a mold cavity;

b) injecting a flowable material into said mold cavity so as to coat at least a portion of said substrate with said flowable material; and

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c) hardening said flowable material to form a coating over at least a portion of said substrate.

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25. The method of claim 24, further comprising the step of heating said flowable material prior to said injecting step (b), and wherein said hardening step (c) comprises cooling said flowable material.

26. The method according to claim 25, wherein said mold cavity is heated prior to said injecting step (b) and cooled during said hardening step (c).

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27. The method according to claim 26, wherein said mold cavity is heated and cooled using heat transfer fluids that circulate proximal to said mold cavity.

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28. The method of claim 25, wherein said mold cavity is heated prior to said injecting step (b) and cooled during said hardening step (c) using a single heat transfer fluid heated by a heat source and cooled by a heat sink.

29. The method according to claim 24, wherein said flowable material comprises a polymer.

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30. The method according to claim 24, wherein said flowable material comprises a carbohydrate.

31. The method according to claim 24, wherein said flowable material comprises a fat.

32. The method according to claim 24, wherein said flowable material comprises a wax.

33. The method according to claim 24, wherein said flowable material comprises gelatin.

34. The method according to claim 33, further comprising heating said gelatin to a temperature above its gel point prior to said injecting step (b), and wherein said hardening step (c) comprises cooling said gelatin to a temperature below its gel point.

35. The method of claim 24, wherein said molded dosage form is substantially free of visible defects.

36. The method of claim 24, wherein substantially all of the flowable material injected into the mold cavity becomes part of the molded dosage form.

37. The method of claim 24, wherein said substrate is a compressed dosage form.

38. The method according to claim 37, wherein said compressed dosage form is prepared by the steps of:

(i) placing a supply of powder in flow communication with a die, said die comprising a die cavity therein;

(ii) applying suction to said die cavity so as to cause powder to flow into said die cavity; and

(iii) compressing said powder in said die cavity so as to form a compressed dosage form.

39. The method of according to claim 37, wherein said compressed dosage form comprises a first medicant.

40. The method according to claim 24 performed while said mold cavity is traveling along a circular path.

41. The method according to claim 24 performed while said mold cavity is traveling along a helical path.

42. The method according to claim 37, wherein said compressed dosage form comprises an insert embedded therein.

43. The method according to claim 42, wherein said insert comprises a thermal-setting material.

44. The method of claim 42, wherein said insert comprises a second medicant.

45. The method according to claim 24, wherein said flowable material comprises a third medicant.

46. A method of applying at least one flowable material to a substrate having first and second portions comprising:

masking said first portion of said substrate;  
exposing said second portion to a mold cavity;  
injecting said flowable material onto said second portion; and  
hardening said flowable material on said second portion of said substrate.

47. A method of applying at least one flowable material to a substrate having first and second portions comprising:

exposing said first portion to a first mold cavity;  
injecting said flowable material onto said first portion;  
hardening said flowable material on said first portion of said substrate;  
retaining said first portion in said first mold cavity.

48. The method according to claim 47, further comprising the steps of:  
transporting said first mold cavity while said first portion is retained therein to a remote location.

49. A method of coating a substrate with first and second flowable materials, comprising the steps of:  
a) enclosing a first portion of said substrate in a first mold cavity;  
b) injecting a first flowable material into said first mold cavity so as to coat said first portion with said first flowable material;

c) hardening said first flowable material to form a coating over said first portion;

d) enclosing a second portion of said substrate in a second mold cavity;

e) injecting a second flowable material into said second mold cavity so as to coat said second portion with said second flowable material; and

f) hardening said second flowable material to form a coating over said second portion.

50. The method according to claim 49, further comprising the steps of:

g) heating said first mold cavity prior to said injection step (b), whereby said first flowable material is injected into a heated mold cavity;

h) cooling said first mold cavity after said injecting step (b);

i) heating said second mold cavity prior to said injection step (e), whereby said second flowable material is also injected into a heated mold cavity; and

j) cooling said second mold cavity after said injecting step (e).

51. The method according to claim 50, wherein said first and second mold cavities are heated during said injecting steps (b) and (e), respectively, and cooled during said hardening steps (c) and (f), respectively.

52. The method according to claim 51, wherein said mold cavities are heated and cooled using heat transfer fluids that circulate proximal to said mold cavities.

53. The method according to claim 49, wherein said first mold cavity travels 360 degrees in a circular path during said injection step (b) and said second mold cavity travels 360 degrees in a circular path during said injection step (e).

54. The method according to claim 49, wherein a single center mold assembly is used for said injection steps (b) and (e).

55. The method according to claim 49, wherein said injection steps (b) and (e) are performed simultaneously in upper and lower mold assemblies connected to a single center mold assembly.

56. The method according to claim 49, wherein said first and second flowable materials comprise gelatin, and said gelatin is heated to a temperature above its gel point prior to said injecting steps (b) and (e), and wherein said hardening steps (c) and (f) comprise cooling said gelatin to a temperature below its gel point.

57. The method according to claim 49, wherein said first and second flowable materials are different colors.

5 58. The method according to claim 49, wherein said injecting step (b) further comprises sealing said second portion of said compressed dosage form so as to provide a boundary between said first flowable material and said second portion.

10 59. The method according to claim 49, wherein said substrate is a compressed dosage form.

60. The method according to claim 59, wherein said compressed dosage form is prepared by the steps of:

15 (i) placing a supply of powder in flow communication with a die, said die comprising a die cavity therein;

(ii) applying suction to said die cavity so as to cause powder to flow into said die cavity; and

(iii) compressing said powder in said die cavity so as to form a compressed dosage form.

20 61. The method according to claim 59, wherein said compressed dosage form comprises a first medicant.

25 62. The method according to claim 49 performed while said mold cavities are traveling along a circular path.

63. The method according to claim 49 performed while said mold cavities are traveling along a helical path.

30 64. The method according to claim 59, wherein said compressed dosage form comprises an insert embedded therein.

65. The method according to claim 64, wherein said insert comprises a thermal-setting material.

35 66. The method of claim 64, wherein said insert comprises a second medicant.

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68. An apparatus for molding substrates comprising a plurality of mold cavities, each mold cavity having an internal surface and comprising an orifice for delivering flowable material to said mold cavity, said orifice being matable with a valve tip that in its closed position forms part of said internal surface.

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70. The apparatus of claim 69, wherein said tubing system further comprises a common flow passageway between said heat sink and said heat source, an energy recovery vessel in fluid communication with said common flow passageway, a plurality of valves disposed in said tubing system between a) said common flow passageway and said heat source and b) said common flow passageway and said heat sink, and a control system for controlling said valves, such that upon activation of said valves by said control system, heat transfer fluid contained in said common flow passageway is transferred to said energy recovery vessel.

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72. The apparatus of claim 70, wherein said energy recovery vessel comprises a hot bladder and a cold bladder.

74. The apparatus of claim 69, wherein said mold cavities are heated and cooled  
35 over a temperature range of about 0 to 100° C in about 1 to 30 seconds.



75. The apparatus of claim 69, wherein the mass and geometry of said mold cavities are such as to have a negligible effect on the time in which said mold cavities are heated and cooled.

5 76. A nozzle system for a molding apparatus, comprising a nozzle and an ejector means, said nozzle surrounding and being concentric with said ejector means.

77. The nozzle system of claim 76, wherein said ejector means comprises an ejector pin.

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78. The nozzle system of claim 76, wherein said ejector means comprises an air passage and said nozzles are retractable.

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79. An apparatus for coating compressed dosage forms, comprising:

a) a mold cavity for enclosing at least a first portion of said compressed dosage form;

b) means for injecting a flowable material into said mold cavity to coat at least said first portion of said compressed dosage form with said flowable material; and

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c) means for hardening said flowable material so as to form a coating over at least said first portion said compressed dosage form.

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80. The apparatus according to claim 79, further comprising (d) means for heating said mold cavity prior to injecting said flowable material into said mold cavity, wherein said hardening means (c) comprises means for cooling said mold cavity.

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81. The apparatus according to claim 80, wherein said heating means (d) and said hardening means (c) comprise a heat source, a heat sink, and a temperature control system, said temperature control system comprising a tubing system disposed proximal to said mold cavities and connected to said heat source and said heat sink for circulating heat transfer fluid through said heat source, through said heat sink, and proximal to said mold cavities, such that said mold cavities may be heated and cooled by said heat transfer fluid.

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82. The apparatus according to claim 79, wherein said flowable material is a first flowable material and said mold cavity is a first mold cavity, said apparatus further comprising:

e) a second mold cavity for enclosing a second portion of said compressed dosage form;

f) means for injecting a second flowable material into said second mold cavity to coat said second portion of said compressed dosage form with said second flowable material; and

g) means for hardening said second flowable material so as to form a coating over said second portion of said compressed dosage form.

83. The apparatus according to claim 82, wherein said first and second flowable materials are different colors.

84. The apparatus according to claim 82, further comprising first means for sealing said second portion of said compressed dosage form while said first portion of said compressed dosage form is being coated, and second means for sealing said first portion of said compressed dosage form while said second portion of said compressed dosage form is being coated.

85. The apparatus according to claim 84, wherein said first and second sealing means are elastomeric collets.

86. The apparatus according to claim 85, wherein said elastomeric collets comprise vents allowing air to escape from said mold cavities during injection of flowable material into said mold cavities.

87. The apparatus according to claim 85, wherein said elastomeric collets comprise a plurality of flexible fingers, said elastomeric collets being attached to a movable support stem, said flexible fingers opening and closing in a radial direction upon movement of said support stem.

88. An apparatus for coating a compressed dosage form having a first portion and a second portion, comprising:

- a) a mold cavity for enclosing said first portion of said compressed dosage form;
- b) a nozzle for injecting a flowable material into said mold cavity to coat said first portion of said compressed dosage form with said flowable material;
- c) a temperature control system capable of heating and cooling said mold cavity;
- and
- d) an elastomeric collet for sealing said second portion of said compressed dosage form while said first portion of said compressed dosage form is being coated.

89. The apparatus of claim 88, further comprising a heat source and a heat sink, said temperature control system comprising a tubing system disposed proximal to said mold cavity and connected to said heat source and said heat sink for circulating heat transfer fluid through said heat source, through said heat sink, and proximal to said mold cavity, such that said mold cavity may be heated and cooled by said heat transfer fluid.

90. The apparatus of claim 89, wherein said tubing system further comprises a common flow passageway between said heat sink and said heat source, an energy recovery vessel in fluid communication with said common flow passageway, a plurality of valves disposed in said tubing system between a) said common flow passageway and said heat source and b) said common flow passageway and said heat sink, and a control system for controlling said valves, such that upon activation of said valves by said control system, heat transfer fluid contained in said common flow passageway is transferred to said energy recovery vessel.

91. The apparatus of claim 90, wherein said energy recovery vessel comprises a fluid reservoir bisected by a piston.

92. The apparatus of claim 90, wherein said energy recovery vessel comprises a hot bladder and a cold bladder.

93. The apparatus according to claim 88, wherein said flowable material is a first flowable material and said mold cavity is a first mold cavity, said apparatus further comprising:

- e) a second mold cavity for enclosing said second portion of said compressed dosage form;
- f) a second nozzle for injecting a second flowable material into said second mold cavity to coat said second portion of said compressed dosage form with said second flowable material; and
- g) a second elastomeric collet for sealing said first portion of said compressed dosage form while said second portion of said compressed dosage form is being coated,

wherein said temperature control system is also capable of heating and cooling said second mold cavity.

94. The apparatus according to claim 88, wherein said elastomeric collet comprises vents allowing air to escape from said mold cavity during injection of flowable material into said mold cavity.

95. The apparatus according to claim 88, wherein said elastomeric collet comprises a plurality of flexible fingers, said elastomeric collet being attached to a movable support stem, said flexible fingers opening and closing in a radial direction upon movement of said support stem.

96. A molding module for molding coatings onto compressed dosage forms, comprising a rotor capable of rotating about a central axis and a plurality of mold units mounted thereon, each mold unit comprising:

a) a mold cavity for enclosing at least a first portion of said compressed dosage form;

b) means for injecting a flowable material into said mold cavity to coat at least said first portion of said compressed dosage form with said flowable material; and

c) means for hardening said flowable material so as to form a coating over at least said first portion said compressed dosage form.

97. The molding module according to claim 96, further comprising (d) means for heating said mold cavity prior to injecting said flowable material into said mold cavity, wherein said hardening means (c) comprises means for cooling said mold cavity.

98. The molding module according to claim 97, wherein said heating means (d) and said hardening means (c) comprise a heat source, a heat sink, and a temperature control system, said temperature control system comprising a tubing system disposed proximal to said mold cavities and connected to said heat source and said heat sink for circulating heat transfer fluid through said heat source, through said heat sink, and proximal to said mold cavities, such that said mold cavities may be heated and cooled by said heat transfer fluid.

99. The molding module according to claim 96, wherein said flowable material is a first flowable material and said mold cavity is a first mold cavity, said mold unit further comprising:

e) a second mold cavity for enclosing a second portion of said compressed dosage form;

f) means for injecting a second flowable material into said second mold cavity to coat said second portion of said compressed dosage form with said second flowable material; and

g) means for hardening said second flowable material so as to form a coating over said second portion of said compressed dosage form.

100. The molding module according to claim 99, wherein said first and second  
5 flowable materials are different colors.

101. The molding module according to claim 99, further comprising first means for sealing said second portion of said compressed dosage form while said first portion of said compressed dosage form is being coated, and second means for sealing said first  
10 portion of said compressed dosage form while said second portion of said compressed dosage form is being coated.

102. The molding module according to claim 101, wherein said first and second  
15 sealing means are elastomeric collets.

103. The molding module according to claim 102, wherein said elastomeric collets  
comprise vents allowing air to escape from said mold cavities during injection of flowable material into said mold cavities.

104. The molding module according to claim 102, wherein said elastomeric collets  
20 comprise a plurality of flexible fingers, said elastomeric collets being attached to a movable support stem, said flexible fingers opening and closing in a radial direction upon movement of said support stem.

105. A molding module for coating a compressed dosage form having a first  
25 portion and a second portion, comprising a rotor capable of rotating about a central axis and a plurality of mold units mounted thereon, each mold unit comprising:  
a) a mold cavity for enclosing said first portion of said compressed dosage form;  
b) a nozzle for injecting a flowable material into said mold cavity to coat said first  
30 portion of said compressed dosage form with said flowable material;  
c) a temperature control system capable of heating and cooling said mold cavity;  
and

d) an elastomeric collet for sealing said second portion of said compressed dosage form while said first portion of said compressed dosage form is being coated.  
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106. The molding module of claim 105, further comprising a heat source and a heat sink, said temperature control system comprising a tubing system disposed proximal to said mold cavity and connected to said heat source and said heat sink for circulating

heat transfer fluid through said heat source, through said heat sink, and proximal to said mold cavity, such that said mold cavity may be heated and cooled by said heat transfer fluid.

5           107. The molding module of claim 106, wherein said tubing system further comprises a common flow passageway between said heat sink and said heat source, an energy recovery vessel in fluid communication with said common flow passageway, a plurality of valves disposed in said tubing system between a) said common flow passageway and said heat source and b) said common flow passageway and said heat sink,  
10           and a control system for controlling said valves, such that upon activation of said valves by said control system, heat transfer fluid contained in said common flow passageway is transferred to said energy recovery vessel.

15           108. The molding module of claim 107, wherein said energy recovery vessel comprises a fluid reservoir bisected by a piston.

            109. The molding module of claim 107, wherein said energy recovery vessel comprises a hot bladder and a cold bladder.

20           110. The molding module according to claim 105, wherein said flowable material is a first flowable material and said mold cavity is a first mold cavity, said mold unit further comprising:

            e) a second mold cavity for enclosing said second portion of said compressed dosage form;

25           f) a second nozzle for injecting a second flowable material into said second mold cavity to coat said second portion of said compressed dosage form with said second flowable material; and

            g) a second elastomeric collet for sealing said first portion of said compressed dosage form while said second portion of said compressed dosage  
30           form is being coated,

wherein said temperature control system is also capable of heating and cooling said second mold cavity.

35           111. The molding module according to claim 105, wherein said elastomeric collet comprises vents allowing air to escape from said mold cavity during injection of flowable material into said mold cavity.

112. The molding module according to claim 105, wherein said elastomeric collet comprises a plurality of flexible fingers, said elastomeric collet being attached to a movable support stem, said flexible fingers opening and closing in a radial direction upon movement of said support stem.

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113. An apparatus for coating compressed dosage forms, comprising:

- a) a lower retainer comprising a plurality of collets mounted therein;
- b) a center mold assembly comprising first and second groups of insert assemblies mounted on opposing sides thereof, each of said insert assemblies of said first group aligned with and facing one of said collets, said lower retainer and said center mold assembly mounted for relative movement so as to bring said first group of insert assemblies into engagement with said collets;
- c) an upper mold assembly comprising upper insert assemblies mounted therein, each of said upper insert assemblies aligned with and facing one of said insert assemblies of said second group, said upper mold assembly and said center mold assembly mounted for relative movement so as to bring said upper insert assemblies into engagement with said second group of insert assemblies.
- d) a supply of flowable material; and
- e) a first passage placing said supply of flowable material in flow communication with said first and second group of insert assemblies, and a valve actuator assembly for controlling the flow of said flowable material to said first and second groups of insert assemblies.

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114. The apparatus according to claim 113, wherein said lower retainer, center mold assembly and upper mold assembly are mounted to a rotor that is capable of rotation about a first axis.

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115. The apparatus according to claim 114, wherein said center mold assembly is mounted for rotation about a second axis, said second axis lying in a plane perpendicular to said first axis, whereby rotation of said center mold assembly about said second axis places each of said insert assemblies in said second group into alignment with and facing one of said collets in said first rotor and places each of said insert assemblies in said first group into alignment with and facing one of said upper insert assemblies in said third rotor.

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116. The apparatus according to claim 113, further comprising means for successively heating and then cooling each of said insert assemblies in said center mold assembly.

5 117. The apparatus according to claim 113, further comprising:

f) a supply of heating fluid;

g) a supply of cooling fluid;

h) second and third passages in heat flow communication with said first and second groups of insert assemblies, respectively, each of said second and third passages in fluid flow communication with said supplies of heating fluid and cooling fluid;

i) third and fourth valves for controlling the flow of heating fluid from said heating fluid supply to second and third passages, respectively;

j) fifth and sixth valves for controlling the flow of cooling fluid from said cooling fluid supply to said second and third passages, respectively.

118. The apparatus according to claim 113, further comprising a flexible seal disposed in each of said collets for isolating said collets from said first group of insert assemblies when said first group of said insert assemblies is brought into engagement with said collets.

119. The apparatus of claim 113, wherein said valve actuator assembly feeds flowable material to only those insert assemblies of the first and second groups of insert assemblies that are facing said lower retainer.

120. The apparatus of claim 113 further comprising an air actuator assembly for controlling the flow of air to said first and second groups of insert assemblies, said air actuator assembly feeding air only to those insert assemblies of the first and second groups of insert assemblies that are facing said upper mold assembly.

121. A dosage form comprising a substrate having an injection molded coating surrounding at least a portion of the substrate.

122. The dosage form of claim 121, wherein said injection molded coating is substantially free of visible defects.

123. A dosage form comprising a substrate having a thermal cycle molded material disposed on at least a portion of the substrate.



124. A dosage form comprising a substrate having a coating thereon, said coating having a thickness of about 100 to about 400 microns; the relative standard deviation in thickness of said coating being less than 30% ; wherein said coating is substantially free of humectants.

125. A dosage form comprising a tablet having a coating thereon, said coating having a thickness of about 100 to about 400 microns, wherein the relative standard deviation in thickness of said dosage form is not more than about 0.35% ; and wherein said coating is substantially free of humectants.

126. The dosage form of claim 125 having a thickness of about 4 to about 10 mm.

127. The dosage form according to claim 125, wherein the diameter of said dosage form is from about 5 to about 15 mm; wherein the relative standard deviation in said diameter is not more than about 0.35%.

128. The dosage form of claim 124, wherein said coating comprises a first portion of a first color; and a second portion of a second color different from said first color.

129. The dosage form of claim 128, wherein said first and second portions meet to form a seam circumscribing said dosage form about midway along a longitudinal axis of said dosage form.

130. The dosage form of claim 128, wherein said first and second portions meet to form a seam circumscribing said dosage form about midway along a radial axis of said dosage form.

131. The dosage form of claim 124, wherein the substrate comprises a compressed dosage form.

132. The dosage form of claim 124, wherein the substrate comprises a capsule.

133. The dosage form of claim 124, wherein the substrate comprises a medicant.

134. The dosage form of claim 124, wherein the coating comprises a medicant.

135. The dosage form of claim 124, wherein the compressed dosage form has a hardness prior to coating of about 1 to about 4 kp/cm<sup>2</sup>.

5 136. The dosage form of claim 124, wherein there is no subcoating between the compressed dosage form and the coating.

137. The method of claim 1, 14, or 24, wherein the flowable material is substantially solvent-free.

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